

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

PRECISION THERAPEUTICS, INC.,)
Plaintiff,)
v.)
KATHLEEN SEBELIUS,)
Secretary of the United States)
Department of Health and Human)
Services,)
Defendant.)
Civil Action No. 09-451

MEMORANDUM ORDER

The complaint filed by Precision Therapeutics, Inc. (“plaintiff” or “PTI”) was received by the clerk of court and was referred to a United States Magistrate Judge for pretrial proceedings in accordance with the Magistrate Judges Act, 28 U.S.C. § 636(b)(1) and Rules 72.1.3 and 72.1.4 of the Local Rules.

The magistrate judge's Report and Recommendation (Docket No. 36), filed on June 25, 2010, recommended that the motion for summary judgment filed by Kathleen Sebelius, Secretary of the United States Department of Health and Human Services ("defendant" or "Sebelius"), be denied, that plaintiff's motion for summary judgment be granted except as to its request for costs and fees, and that the decisions of the Secretary be remanded to the relevant administrative law judges (the "ALJs").

Remand was recommended in light of the ALJs' failure to weigh or address their rejection of contrary probative evidence regarding the patient benefits of PTI's chemotherapy assay laboratory test, and their reliance on unsubstantiated assumptions integral to conclusions that the assay is not "reasonable and necessary", and therefore not entitled to Medicare reimbursement, under Part B of the Medicare program. The Report concluded that the court cannot complete meaningful substantial evidence review at this time, and recommended the court remand the decisions for further consideration by the ALJs.

Service was made on all counsel of record. Defendant's objections to the Report and Recommendation were filed on August 24, 2010, and plaintiff's response followed on September 14, 2010. After review of the pleadings and documents in the case, together with the Report and Recommendation and the objections and response thereto, the court observes that defendant devotes much of its objections to observations and assertions regarding the standards applicable to a court's "invalidat[ion]" of an agency action, "substitut[ion] of its judgment for the agency's" or "revers[al of] an agency decision." Defendant's objections at 4 (detailing standards); see e.g., id. at 6 (asserting impermissible reweighing of evidence); id. at 14; id. at 15 (objecting, in closing, to impermissible "reweighing"). The salient point is, of course, that the Report and Recommendation neither substitutes the court's judgment for the ALJ's judgment, nor recommends *reversal* of an agency decision. To the contrary, the Report simply concludes that, under the appropriate standard of review, the court must *remand* to the ALJs for further consideration and elucidation, due to their failure to reflect or address apparently probative contrary evidence of patient benefits and reliance on unsubstantiated assumptions.

To the extent defendant understands the requirement that its determinations be supported by "substantial evidence" to mandate only that an administrative law judge "simply . . . clearly disclose the grounds upon which [she or he] acted", *i.e.*, the supportive evidence - without regard to the degree of consideration of contrary probative evidence reflected in the determination - defendant errs. Compare defendant's objections at 4-5 with Report and Recommendation at 2, n.1, 13-14 (explaining requirements, under applicable precedent, that an administrative law judge explain why he or she rejected contrary probative evidence and that his or her decision reflect consideration of all important aspects of issue).¹

The Report and Recommendation provides a detailed review of extensive, apparently contrary probative evidence which the ALJs appear to have rejected without explanation, as well as the implication of apparently unsubstantiated or unexplained assumptions. As noted in plaintiff's response to the objections, defendant failed to identify language in the ALJs' decisions sufficient to address these omissions. See generally Reply to Defendant's Objections. The missing explanation and reasoning cannot be supplied in the briefing or the objections. The reasons for rejecting or giving minimal weight to certain evidence and for making certain assumptions must be set forth by the ALJ. The court is unable to undertake meaningful review of the ALJs' decisions before it.

1. Cf., e.g., Defendant's objections at 15 (asserting that "even if the record contained many affidavits of physicians disagreeing with the ASCO conclusions, it would certainly still be reasonable for a fact-finder" to concur with that organization). Again, the salient point is that the Report did not reach the reasonableness of the ALJs' conclusions because their failure to articulate their reasons for weighing and rejecting contrary probative evidence, such as the extensive written physician testimony discussed in footnote19 of the Report and Recommendation (Docket no. at n. 19), precluded meaningful review.

There is no finding that the ALJs' decisions are not supported by substantial evidence; rather, the finding is that this court is unable to conduct a meaningful review of the ALJs' decisions. Defendant requested that if the court determined a remand is necessary, only the decisions rendered by ALJ Steele be remanded. Defendant argues that ALJ Jones' decision provided more substance and should be viewed differently than the decisions rendered by ALJ Steele. While it is true that ALJ Jones' decision was more robust than ALJ Steele's decisions, ALJ Jones still failed to explain why contrary evidence was rejected or given little weight. ALJ Jones recited certain contrary evidence in the summary of evidence, but, with the exception of the test requisition forms, in the discussion and conclusions portion of the decision did not explain why contrary evidence was rejected or given little weight. Under those circumstances a remand is necessary for the decision rendered by ALJ Jones, as well as the decisions of ALJ Steele.

ACCORDINGLY, the following Order is entered:

AND NOW, this 28th day of September, 2010:

IT IS HEREBY ORDERED that defendant's Motion for Summary Judgment (Docket No. 27) is **DENIED**.

IT IS FURTHER ORDERED that plaintiff's Motion for Summary Judgment (Docket No. 21) is **GRANTED IN PART** with respect to the request for a remand and is **DENIED** in all other respects.

IT IS FURTHER ORDERED that the Report and Recommendation of Magistrate Judge Lenihan, with the exception of the form of order, is adopted as the opinion of the court. The decisions are remanded FORTHWITH to the defendant for further proceedings consistent with this order. The clerk shall mark this case closed.

/s/ Joy Flowers Conti
Joy Flowers Conti
United States District Judge

Dated: September 28th, 2010